limitations of the base claim and any intervening claim. Hence, claims 47 and 48 are now in condition for allowance. Re-examination and reconsideration of pending claims 19-27 and 35-46, as amended, are respectfully requested.

Rejection Under 35 U.S.C. § 112

Claims 36 and 41 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have amended claim 36 to now recite that "the electrodes are adapted to transmit" as recommended by the Examiner. Claims 40 and 41 have been amended to depend from claim 39 so that proper antecedent basis for the term "the limit mechanism" is provided. As such, Applicants respectfully request the withdrawal of the 35 U.S.C. § 112 rejections.

Rejection Under 35 U.S.C. § 102/103

Claims 19, 20, 23, 24, 26, 27, and 35-37 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,505,730 issued to Edwards. Claims 19-22, 24-27, 34-39, and 42-46 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,283,961 issued to Underwood et al. Claims 19-22, 24-27, 35-37, and 39 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,035,238 issued to Ingle et al. Claims 21, 25, 42, 45, and 46 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Edwards in view of Ingle et al. or Underwood et al. Claims 25, 38, and 42-46 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ingle et al. in view of Underwood et al. Such rejections are now moot as described below.

To expedite prosecution of this case and more clearly claim the present invention, Applicants have amended claim 19 to recite a device for effecting a desired contraction of a discrete target region of a tissue so as to treat incontinence, the target region having a target region size and shape. The device of claim 19 now recites a vaginal probe having a treatment surface, the treatment surface size and shape corresponding to the size and shape of the target region and having a length of at least 10

mm and width of at least 5 mm. Further, at least one protruding element having a radius of curvature in a range from about 0.05 mm to about 2 mm is disposed along the treatment surface for transmitting energy from the treatment surface to the target region without moving the probe such that the energy effects the desired contraction of the target tissue without ablating the target tissue, and so that the contracted target tissue inhibits the incontinence. Support for these limitations may be found throughout the originally filed application and in particular with reference to Figs. 5 and 5A and associated text on page 12, line 6 through page 13, line 5. Such elements have not been shown.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. § 102. M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claims." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The cited art references are clearly distinguishable from claim 19 in various aspects.

The Edwards and Underwood et al. references fail to teach much less remotely suggest the structural limitation of at least one protruding element having a radius of curvature in a range from about 0.05 mm to about 2 mm as now claimed by claim 19. Further, the Edwards reference describes a thin layer ablation apparatus that is specifically designed to apply RF ablation energy to an inner layer of an organ in the body, particularly an endometrium of a uterus to treat menorrhagia (i.e., excessive menstrual bleeding). See Figs. 2B and 3; col. 1, lines 6-9. The Underwood et al. patent describes a planar ablation probe (404) having a plurality of electrodes (416) for applying ablative RF energy to spinal tissue for treating herniated discs. See Figs. 20 and 21B; col. 1, lines 45-49; col. 28, lines 62-65.. In contrast, the presently claimed device provides a vaginal probe that contracts the target tissue without ablating the target tissue and so that the contracted target tissue inhibits urinary incontinence. This revolutionary and potentially non-invasive vaginal probe for urinary stress incontinence recited by claim 19 is not disclosed or suggested in either the Edwards or Underwood et al. references. Moreover, the Underwood et al. spinal probe electrodes are translated

relative to the target tissue as shown by motion vector 523 in Figs. 26 and 27. The present invention in contrast is directed to a static urinary incontinence device where energy is transmitted without moving the probe.

With respect to the Ingle et al. reference, Applicants are now claiming a vaginal probe having at least one protruding element having a radius of curvature in a range from about 0.05 mm to about 2 mm. Significantly, by setting a radius of curvature range of the rounded electrodes the depth of penetration of treatment energy may be controlled through tissue which lies within a particular treatment distance of the probe so that the depth of tissue treatment may be varied. For example, a protruding element having a radius of curvature in a range from about 0.05 mm to about 2 mm may allow for heating of the tissue to a depth in the range between 0.5 and 10 mm from the engaged tissue surface. If the present rejection is maintained, Applicants request that the Examiner identify where Ingle et al (or any other cited reference) teaches or suggests this distinct structural limitation.

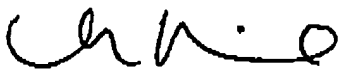
"Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Absent a showing in a single prior art reference for a static urinary stress incontinence device comprising a vaginal probe having a protruding element having a radius of curvature in a range from about 0.05 mm to about 2 mm, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejections and allowance of independent claim 19 (and dependent claims 20-27 and 35-41).

Independent claim 42 has been amended so that it is now directed at a static incontinence device comprising a vaginal probe body having at least two protruding electrodes having a rounded surface and a radius of curvature in a range from about 0.05 mm to about 2 mm. As such claim 42 (and dependent claims 43-46) should be allowable for many of the reasons given above with respect to claim 19.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is urged. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at 650-326-2400.

Respectfully submitted,



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APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 19, 36, 40, 41, and 42. Please add new claims 47 and 48.

19. (Twice amended) A device for effecting a desired contraction of a discrete target region of a tissue so as to treat incontinence, the target region having a target region size and shape, the device comprising:

a vaginal probe having a treatment surface, the treatment surface size and shape corresponding to the size and shape of the target region and having a length of at least 10 mm and a width of at least 5 mm; and

at least one protruding element having a radius of curvature in a range from about 0.05 mm to about 2 mm disposed along the treatment surface for transmitting energy from the treatment surface to the target region without moving the probe such that the energy effects the desired contraction of the target tissue without ablating the target tissue, and so that the contracted target tissue inhibits the incontinence.

36. (Amended) The device of claim 35, wherein the electrodes are adapted to transmit bipolar electrical energy to the target region.

40. (Amended) The probe of claim 39 [38], wherein the limit mechanism comprises a thermal mass, the at least one element comprising a heat transfer surface thermally coupled to the thermal mass, the thermal mass transferring a significant portion of the energy when the heat transfer surface cools from a safe tissue temperature toward body temperature.

41. (Amended) The probe of claim 39 [38], wherein the limit mechanism comprises a reaction mass that reacts to transfer the energy and which is depleted when the energy is transferred.

42. (Amended) A device for heating a target fascial tissue so as to treat incontinence, the target tissue having a fascial surface, the device comprising:

a vaginal probe body having a treatment surface, the treatment surface being oriented for engaging the fascial surface, the probe body having a length in a range from about 10 mm to about 50 mm and a width in a range from about 5 mm to about 30 mm; and

at least two protruding electrodes having a rounded surface and a radius of curvature in a range from about 0.05 mm to about 2 mm disposed over the treatment surface for transmitting bipolar electrical energy into the engaged target tissue without moving the probe such that the energy heats the target tissue so as inhibit the incontinence.

47. (New) A device for effecting a desired contraction of a discrete target region of a tissue so as to treat incontinence, the target region having a target region size and shape, the device comprising:

a probe having a treatment surface, the treatment surface size and shape corresponding to the size and shape of the target region and having a length of at least 10 mm and a width of at least 5 mm; and

at least one element disposed along the treatment surface for transmitting energy from the treatment surface to the target region without moving the probe such that the energy effects the desired contraction of the target tissue without ablating the target tissue, and so that the contracted target tissue inhibits the incontinence;

wherein the at least one element has a mechanism that limits transmitted energy so as to avoid ablation of the target tissue, wherein the limit mechanism comprises a thermal mass, the at least one element comprising a heat transfer surface thermally coupled to the thermal mass, the thermal mass transferring a significant portion of the energy when the heat transfer surface cools from a safe tissue temperature toward body temperature.

48. (New) A device for effecting a desired contraction of a discrete target region of a tissue so as to treat incontinence, the target region having a target region size and shape, the device comprising:

a probe having a treatment surface, the treatment surface size and shape corresponding to the size and shape of the target region and having a length of at least 10 mm and a width of at least 5 mm; and

at least one element disposed along the treatment surface for transmitting energy from the treatment surface to the target region without moving the probe such that the energy effects the desired contraction of the target tissue without ablating the target tissue, and so that the contracted target tissue inhibits the incontinence;

wherein the at least one element has a mechanism that limits transmitted energy so as to avoid ablation of the target tissue, wherein the limit mechanism comprises a reaction mass that reacts to transfer the energy and which is depleted when the energy is transferred.

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